ULTRADENT PRODUCTS, INC.

K051750

SEP 19 2005

SUMMARY OF SAFETY AND EFFECTIVENESS & STATEMENT OF COMPARISON

(as per 21 CFR 807.92c)

1) Submitted by:	Tammy Lavery Ultradent Products, Inc. 505 West 10200 South South Jordan, UT 98004 USA
2) Establishment Registration No:	1718912
3) Date Prepared:	06/21/05
4) Product Proprietary Name:	Flor-Opal Varnish
5) Device Common Name:	Dental Varnish
6) Device Classification Name:	Cavity Varnish (21 CFR 872.3260)
7) Device Class:	Class II (76LBH)
8) Substantial equivalence:	The Flor-Opal Varnish which is to be manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, Utah 84095, is substantially equivalent to the legally-marketed devices as noted on the attached document. (Refer to section IV of this 510(k) Submission for labeling and added detail for each of the predicates identified).

The 510(k) Substantial Equivalence Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1) The Flor-Opal varnish and the products listed have the same intended use, that being as varnish on sensitive teeth, over exposed dentin, under temporary restoratives and cements, and on exposed dentin on roots.

2) The technological characteristics for this product are the virtually the same as the predicate devices listed. No significant variation has been implemented.

3) Descriptive information per the table noted below further shows that the materials from the listed predicate devices are substantially equivalent as they are used for the same purpose and have the relatively the same properties, etc.

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4) As noted above, the Substantial Equivalence Decision-Making Process Chart was used.

See below for a comparison table showing similarities and differences from the predicate devices listed supporting substantial equivalence.

Similarities:

Predicate Devices	Flor-Opal Varnish
[redacted]	[redacted]
5% sodium fluoride in a solvent base	5% sodium fluoride in a solvent base
Dentinal tubule obturator for the reduction in dental hypersensitivity	Dentinal tubule obturator for the reduction in dental hypersensitivity
Dentist administered	Dentist administered

Differences:

Predicate Devices	Flor-Opal Varnish
[redacted]	[redacted]
No significant differences noted with any of the predicate devices and the Flor-Opal Varnish identified. All products reviewed have very similar chemical ingredients. All have the same concentration of the active ingredient.	

Conclusion:

Per the review noted above in accordance with the guidance document, the Flor-Opal Varnish is found to be substantially equivalent to the identified predicate devices.

6/23/05

Peter Allred **Date**
Research and Development Chemist

Tammy Lavery 6/23/05

Tammy Lavery **Date**
Regulatory Affairs Senior Manager

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2005

Ms. Tammy Lavery
Regulatory Affairs Senior Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

Re: K051750
Trade/Device Name: Flor-Opal Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: August 15, 2005
Received: August 26, 2005

Dear Ms. Lavery:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051750

INDICATIONS FOR USE

510(k) Number (if known): Unknown K051750

Device Name: Flor-Opal Varnish

Indications for use:

Intended for use as a varnish on sensitive teeth, over exposed dentin under temporary restoratives and cements where post-operative sensitivity is a concern and to improve quality and functionality of restorations when used in conjunction with dental restoratives and cements.

Product is also intended for use to seal dentinal tubules in cavity preparations or on sensitive root surfaces.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K051750

(Optional Format 1-2-9